DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 November 2008 has been entered.

Election/Restrictions/Rejoinder

2. Claims 2, 5, 8, 11, 14-17, 19, 21, 23, 25, 27, 29, 31 and newly added claims 72-73 (see below) directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 33-58 and 71, directed to processes using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 63-70, directed to the invention of Group IV does not require all the limitations of an allowable product claim, and has **NOT** been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement among groups I-III and V as set forth in the Office action mailed on 23 February 2006 is HEREBY WITHDRAWN**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with William J. Simmons, Ph.D. on 13 February 2009.

The claims are amended as follows.

1. (cancelled).

2. (currently amended) An isolated antibody or ~~epitope-binding~~ fragment thereof that specifically binds CD33, comprising at least one heavy chain variable region and at least one light chain variable region, wherein said heavy chain variable region comprises three complementarity-determining regions having the amino acid sequences of SEQ ID NOs:1-3,

and wherein said light chain variable region comprises three complementarity-determining regions having the amino acid sequences of SEQ ID NOs:4-6.

3-4. (cancelled).

5. (currently amended) The antibody or ~~epitope-binding~~ fragment thereof of claim 2, wherein said heavy chain variable region comprises the amino acid sequence of SEQ ID NO:7.

6-7. (cancelled).

8. (currently amended) The antibody or ~~epitope-binding~~ fragment thereof of claim 2, wherein said light chain variable region comprises the amino acid sequence of SEQ ID NO:8.

9-10. (cancelled).

11. (currently amended) The antibody or ~~epitope-binding~~ fragment thereof of claim 2, wherein said heavy chain variable region comprises the amino acid sequence of SEQ ID NO:9.

12-13. (cancelled).

14. (currently amended) The antibody or ~~epitope-binding~~ fragment thereof of claim 2, wherein said light chain variable region comprises the amino acid sequence of SEQ ID NO:10.

15. (currently amended) A purified antibody or ~~epitope-binding~~ fragment thereof that specifically binds to CD33, wherein the heavy chain variable region portion of said antibody or ~~epitope-binding~~ fragment comprises the amino acid sequence of SEQ ID NO:7

and wherein the light chain variable region portion of said antibody or ~~epitope-binding~~ fragment comprises the amino acid sequence of SEQ ID NO:8.

16. (currently amended) A humanized or resurfaced antibody, or ~~an epitope-binding~~ a fragment thereof, that specifically binds to CD33, wherein the heavy chain variable region portion of said antibody or ~~epitope-binding~~ fragment comprises the amino acid sequence of SEQ ID NO:9 and wherein the light chain variable region portion of said antibody or ~~epitope-binding~~ fragment comprises the amino acid sequence of SEQ ID NO:10.

17. (currently amended) An immunoconjugate comprising the antibody or ~~epitope-binding~~ fragment thereof of claim [[1]] 2 linked to a drug or prodrug.

18. (cancelled).

19. (previously presented) The immunoconjugate of claim 17, wherein said drug or prodrug is selected from the group consisting of a maytansinoid, a taxoid, CC-1065, a CC-1065 analog, dolastatin, a dolastatin analog, methotrexate, daunorubicin, doxorubicin, vincristine, vinblastine, melphalan, mitomycin C, chlorambucil, and calicheamicin.

20. (cancelled).

21. (currently amended) A composition comprising the antibody or ~~epitope-binding~~ fragment thereof of claim [[1]] 2 and a drug or prodrug.

22. (cancelled).

23. (currently amended) A pharmaceutical composition comprising the antibody or ~~epitope-binding~~ fragment thereof of claim [[1]] 2, and a pharmaceutically acceptable agent.

24. (cancelled).

25. (original) A pharmaceutical composition comprising the immunoconjugate of claim 17, and a pharmaceutically acceptable agent.

26. (cancelled).

27. (original) A pharmaceutical composition comprising the composition of claim 21, and a pharmaceutically acceptable agent.

28. (cancelled).

29. (currently amended) A diagnostic reagent comprising the antibody of claim [[1]] 2, wherein said antibody or antibody fragment is labeled.

30. (cancelled).

31. (original) The diagnostic reagent of claim 29, wherein said label is selected from the group consisting of a biotin label, an enzyme label, a radio-label, a fluorophore, a chromophore, an imaging agent and a metal ion.

32. (cancelled).

33. (presently rejoined-currently amended) A method for inhibiting the growth of a cell expressing CD33 comprising contacting said cell with the antibody or ~~epitope-binding~~ fragment thereof of claim ~~1 or~~ 2.

34. (presently rejoined-currently amended) A method for inhibiting the growth of a cell expressing CD33 comprising contacting said cell with the immunoconjugate of claim 17 ~~or 18~~.

35. (presently rejoined-currently amended) A method for inhibiting the growth of a cell expressing CD33 comprising contacting said cell with the composition of claim 21 ~~or 22~~.

36. (presently rejoined-currently amended) A method for inhibiting the growth of a cell expressing CD33 comprising contacting said cell with a pharmaceutical composition selected from ~~claims 23-28~~claim 23, 25 or 27.

37. (presently rejoined-currently amended) A method for treating a subject having a disease wherein CD33 is expressed, comprising administering to said subject an effective amount of the antibody or ~~epitope-binding~~ fragment thereof of claim 1~~ or 2~~.

38. (presently rejoined-currently amended) A method for treating a subject having a disease wherein CD33 is expressed, comprising administering to said subject an effective amount of the immunoconjugate of claim 17~~ or 18~~.

39. (presently rejoined-currently amended) A method for treating a subject having a disease wherein CD33 is expressed, comprising administering to said subject an effective amount of the composition of claim 21~~ or 22~~.

40. (presently rejoined-currently amended) A method for treating a subject having a disease wherein CD33 is expressed, comprising administering to said subject an effective amount of the pharmaceutical composition of claim 23~~ or 24~~.

41. (presently rejoined-currently amended) A method for treating a subject having a disease wherein CD33 is expressed, comprising administering to said subject an effective amount of the pharmaceutical composition of claim 25 ~~or 26~~.

42. (presently rejoined-currently amended) A method for treating a subject having a disease wherein CD33 is expressed, comprising administering to said subject an effective amount of the pharmaceutical composition of claim 27 ~~or 28~~.

43. (presently rejoined-currently amended) A method for treating a subject having a disease wherein CD33 is expressed, comprising contacting one or more cells of said subject *ex vivo* with an effective amount of the antibody or ~~epitope-binding~~ fragment thereof of claim ~~1 or~~ 2.

44. (presently rejoined-currently amended) A method for treating a subject having a disease wherein CD33 is expressed, comprising contacting one or more cells of said subject *ex vivo* with an effective amount of an immunoconjugate of claim 17 ~~or 18~~.

45. (presently rejoined-currently amended) A method for treating a subject having a disease wherein CD33 is expressed, comprising contacting one or more cells of said subject *ex vivo* with an effective amount of a composition of claim 21 ~~or 22~~.

46. (presently rejoined-currently amended) A method for treating a subject having a disease wherein CD33 is expressed, comprising contacting one or more cells of said subject *ex vivo* with an effective amount of a pharmaceutical composition selected from ~~claims 23-28~~claim 23, 25 or 27.

47. (presently rejoined) The method of treatment of claim 37, wherein said disease is a disease selected from the group consisting of myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

48. (presently rejoined) The method of treatment of claim 38, wherein said disease is a disease selected from the group consisting of myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

49. (presently rejoined) The method of treatment of claim 39, wherein said disease is a disease selected from the group consisting of myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

50. (presently rejoined) The method of treatment of claim 40, wherein said disease is a disease selected from the group consisting of myelodysplastic syndrome

(MDS), acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

51. (presently rejoined) The method of treatment of claim 41, wherein said disease is a disease selected from the group consisting of myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

52. (presently rejoined) The method of treatment of claim 42, wherein said disease is a disease selected from the group consisting of myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

53. (presently rejoined) The method of treatment of claim 43, wherein said disease is a disease selected from the group consisting of myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

54. (presently rejoined) The method of treatment of claim 44, wherein said disease is a disease selected from the group consisting of myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

55. (presently rejoined) The method of treatment of claim 45, wherein said disease is a disease selected from the group consisting of myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

56. (presently rejoined) The method of treatment of claim 46, wherein said disease is a disease selected from the group consisting of myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

57. (presently rejoined-currently amended) A method of determining whether a biological sample contains a myelogenous cancer cell, comprising:

(a) contacting said biological sample with a diagnostic reagent of claim 29 ~~or 30~~, and

(b) detecting the distribution of said reagent within said sample.

58. (previously presented) The method of claim 57, wherein said myelogenous cancer cell is a cell of a cancer selected from the group consisting of acute myeloid leukemia (AML), chronic myeloid leukemia (CML) and pro-myelocytic leukemia (PML).

59-70. (cancelled).

71. (presently rejoined-currently amended) A method for obtaining CD33 from a biological material, said method comprising:

(a) contacting a biological material with the antibody or ~~epitope-binding~~ fragment thereof of claim ~~1 or~~ 2,

(b) permitting the antibody or ~~epitope-binding~~ fragment of claim ~~1 or~~ 2 to bind to CD33 in said biological material, and

(c) isolating the antibody or ~~epitope-binding~~ fragment bound to CD33 from the biological material, thereby obtaining CD33 from a biological material.

72. (New) An isolated antibody or antibody fragment thereof that specifically binds to CD33, comprising a heavy chain variable region and a light chain variable region, wherein said heavy chain variable region comprises heavy chain complementarity-determining regions comprising the amino acid sequences of SEQ ID NOs:1-3, and wherein said light chain variable region comprises the amino acid sequence of SEQ ID NO:8.

73. (New) An isolated antibody or antibody fragment thereof that specifically binds to CD33, comprising a heavy chain variable region and a light chain variable region, wherein said heavy chain variable region comprises the amino acid sequence of SEQ ID NO:7, and wherein said light chain variable region comprises light chain

complementarity-determining regions comprising the amino acid sequences of SEQ ID NOs:4-6.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643